PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference AP101517	**FOR FURTHER ACTION**	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/FI 03/00850	International filing date *(day/month/year)* 10.11.2003	Priority date *(day/month/year)* 08.11.2002
International Patent Classification (IPC) or both national classification and IPC A61K31/4164		
Applicant OY JUVANTIA PHARMA LTD et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 4 sheets, including this cover sheet.

   ☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the opinion
   - II ☐ Priority
   - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
26.05.2004	22.11.2004
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer Beeck, M Telephone No. +49 89 2399-8473

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/FI 03/00850

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:

Description, Pages

1-9 as originally filed

Claims, Numbers

1-10 as originally filed

Drawings, Sheets

1/1 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

   These elements were available or furnished to this Authority in the following language: , which is:

   ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).

   ☐ the language of publication of the international application (under Rule 48.3(b)).

   ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

   ☐ contained in the international application in written form.

   ☐ filed together with the international application in computer readable form.

   ☐ furnished subsequently to this Authority in written form.

   ☐ furnished subsequently to this Authority in computer readable form.

   ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

   ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

   ☐ the description, pages:

   ☐ the claims, Nos.:

   ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

   (Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-10
	No:	Claims	
Inventive step (IS)	Yes:	Claims	1-10
	No:	Claims	
Industrial applicability (IA)	Yes:	Claims	1-10
	No:	Claims	

2. Citations and explanations

   see separate sheet

D1: RISTO HUUPPONEN ET AL: "Buccal delivery of an alpha2-adrenergic receptor antagoist, atipamezole, in humans" CLIN PHARMACOL THER, vol. 58, 1995, pages 506-511, XP002269436

D2: "Atipamezole Antisedan. Alpha2-Adrenoceptor Antagonist Treatment of Male Sexual Dysfunction" DRUGS OF THE FUTURE, vol. 21, no. 5, 1996, pages 534-535, XP002269437

D3: L.A. SORBERA ET AL: "Fipamezole Hydrochloride. Antiparkinsonian alpha2-Adrenoceptor Antagonist" DRUGS OF THE FUTURE, vol. 28, no. 1, 2003, pages 14-17, XP002269438

D4: US-A-5 434 177 (RIEKKINEN PAAVO J ET AL) 18 July 1995 (1995-07-18)

D5: US-A-5 498 623 (SALONEN JARMO S ET AL) 12 March 1996 (1996-03-12)

SECTION V:

1) The examination has been carried out assuming that the priority is valid, so that P-document D3 has not been taken into consideration.

2) The subject-matter of the claims is novel.

3) Closest prior art document for the assessment of inventive step is D1 which describes oromucosal formulations of atipamezole.

The subject-matter of claims 1 and 10 differs therefrom in that R_1 is halogen or hydroxy.

Since halogen or hydroxy are not bioisosteric with hydrogen in atipamezole, the subject-matter of the claims was not obvious for the person skilled in the art.

Therefore the subject-matter of the claims involves an inventive step.